IN THE MATTER OF

PHARMACEUTICAL SERVICES OF **AMERICA**

PERMIT NO.: P01873

Respondent-Pharmacy

BEFORE THE

MARYLAND BOARD

OF PHARMACY

Case No.: 20-075

CONSENT ORDER

On January 28, 2021, the Maryland Board of Pharmacy ("the Board") charged PHARMACEUTICAL SERVICES OF AMERICA ("the Respondent-Pharmacy"), Permit Number P01873, under the Maryland Pharmacy Act, (the "Act") Md. Code Ann., Health Occ. §§ 12-101 et seq. (2014 Repl. Vol. and 2019 Supp.) and certain provisions of the Board's regulations found at Md. Code Regs. ("COMAR") 10.34 et seq.

The pertinent provisions of the Act provide as follows:

Health Occ. § 12-403. Required Standards.

- In general. Except as otherwise provided in this section, a pharmacy (c) for which a pharmacy permit has been issued under this title:
 - Shall be operated in compliance with the law and with the rules (1) and regulations of the Board;
 - Shall be located and equipped so that the pharmacy may be (2) operated without endangering the public health or safety:
 - (3) Shall ensure that a licensed pharmacist be immediately available on the premises to provide pharmacy services at all times the pharmacy is in operation;

(11)(ii)Shall:

. . . .

- 1. Be equipped with the minimum equipment and appliances specified by the Board under this section; and
- 2. Be kept in a clean and orderly manner;
- (12) Shall store all prescription or nonprescription drugs or devices properly and safely subject to the rules and regulations adopted by the Board;
- (16) Shall provide such personnel, automation, and technology as are necessary to comply with the labeling requirements specified in § 12-505 of this title;
- (21) Shall dispense or dispose of prescription drugs or medical supplies in accordance with Title 15, Subtitle 6 of the Health-General Article[.]

Health Occ. § 12-413. Entry and inspection.

. . . .

- (a) During business hours, the Secretary, the Board, or the agents of either may enter any permit holder's pharmacy and inspect for compliance with federal and State laws and regulations:
 - (1) Any drugs or devices, dentifrices, domestic remedies, and toilet articles that are in the pharmacy;
 - (2) Any records or publications that are required to be kept by a pharmacy under this title; and
 - (3) The facility.
- (c) A person may not hinder an inspection or an investigation conducted under this section.

Health Occ. § 12-505. Labeling requirements for prescription medications.

(a) Except for a drug or device dispensed to an inpatient in a hospital or related institution, each container of a drug or device dispensed shall be labeled in accordance with this section.

- (b) In addition to any other information required by law, the label shall include:
 - (1) The date the prescription is filled;

Health Gen. § 21-221. Prescription Drug Labeling.

- (a) A drug that is dispensed under a prescription shall bear a label that states:
 - (1) The name and address of the dispenser;

The pertinent provisions of COMAR 10.34 provide as follows:

10.34.05.02. Prescription Area

- A. The pharmacy permit holder shall:
 - (2) Provide a means of securing the prescription area;
 - (4) Monitor unauthorized or emergency entry after the prescription area has been secured by the pharmacist; and

C. Security

. . . .

- (1) A pharmacy shall be secure from unauthorized entry as follows:
 - (a) Access from outside the premises shall be:
 - (ii) Well controlled
- (2) A pharmacy shall be equipped with:
 - (a) An alarm system to detect entry after hours;

(e) A security system to protect the integrity and confidentiality of data and documents limited to authorized personnel[.]

10.34.05.03. Pharmacy Operations

. . . .

A. A pharmacist shall be immediately available on the premises to provide pharmacy services at all times the pharmacy is in operation.

10.34.12.01. Removal of Expired Medications

B. A wholesale distributor, pharmacist, or pharmacy shall have adequate and credible provisions for return of outdated drugs, including but not limited to partials, through its wholesale distributor or reverse distributor.

10.34.14.02. Opening a Pharmacy

B. A pharmacy may not be located in a residence.

On March 10, 2021, the Respondent-Pharmacy's owner, Mr. Danesh. R.Ph.. and Karen Malinowski, Administrative Prosecutor, attended a Case Resolution Conference ("CRC") with members of the Board in an effort to resolve the pending charges in lieu of an evidentiary hearing. As a result of the CRC, the Respondent-Pharmacy and the State agreed to enter into this Consent Order consisting of Findings of Fact, Conclusions of Law. and Order.

I. FINDINGS OF FACT

The Board finds:

- 1. At all times relevant hereto, the Respondent-Pharmacy had a permit to operate as a pharmacy in the State of Maryland. The Respondent-Pharmacy was originally issued a permit on or about March 7, 1995. The Respondent-Pharmacy's permit expires on May 31, 2022.
- 2. At all times relevant, the Respondent-Pharmacy has operated as a community pharmacy in the basement of the Owner-Pharmacist's primary residence. The only employee of the Respondent-Pharmacy is the Owner-Pharmacist.

Current Complaints/Issues

June 2020 Complaint

3. On or about June 4, 2020, the Board received a complaint from an out-of-state Pharmacy Network. The complaint stated in part:

In May of 2020, Pharmaceutical Svcs of America was up for recredentialing with [out-of-state Pharmacy Network]. recredentialing team reviewed the pharmacy information listed in the pharmacy NCPDP^[1] profile. The pharmacy address was listed . . . A Google image search identifies this address as a private residence. The pharmacy also lists the fax number as 111-111-1111, an invalid fax number. Due to these initial findings, a member of Jout-of-state Pharmacy Network] contacted the pharmacy owner and was told they are "operating out of their basement." When Jout-of-state Pharmacy Network] called the pharmacy, the call goes to the residence and when asking to speak to the pharmacy, it took a minute for them to realize it was not a personal call [Out-of-state Pharmacy Network] called and emailed the MD Board of Pharmacy to inquire about the regulations of operating a pharmacy out of a residence. [Out-of-state Pharmacy Network] received a reply on 05/21/2020 that read, "Pursuant to Code of Maryland Regulations (COMAR) 10.34.14.02B, pharmacies located in Maryland 'may not be located in a residence.""

NCPDP = National Counsel for Prescription Drug Programs - The NCPDP assigns a unique, national identification number to every licensed pharmacy in the United States and its territories.

4. After receiving this complaint, the Board opened an investigation.

- 5. On or about July 14, 2020, a Board inspector ("Inspector A") conducted a virtual² annual community pharmacy inspection (the "annual inspection") of the Respondent-Pharmacy. In addition to completing the Community Pharmacy Inspection Form ("Inspection Form"), Inspector A formalized her observations in a July 15, 2020 memo ("2020 Memo"). The Inspection Form and the 2020 Memo noted the following issues:
 - a. The Pharmacy-Respondent is located in the basement of a residence.
 - b. The Owner-Pharmacist stated that prescriptions are faxed or called into the pharmacy and are delivered via US mail. The Owner-Pharmacist also stated that the pharmacy accepts walk-in prescription drop off and pick up.
 - c. There is no public signage to show there is a pharmacy in the basement of the residence, there is only a sign on the basement door that has the pharmacy's name and hours of operation. You can only see the sign after you have walked on the property and gone down the basement stairs.
 - d. The Owner-Pharmacist noted that there have been no upgrades or modifications to the Respondent-Pharmacy's security system. Photos submitted by the Owner-Pharmacist show evidence of a security camera mounted on a tree in the backyard and mounted on what appears to be part of the house. The Owner-Pharmacist also submitted photographs of a standard lock and added deadbolt on the exterior door to the basement,³ and a metal gate inside the basement that separates the pharmacy dispensing area from the rest of the basement.

² Due to an ongoing state of emergency and catastrophic health emergency, the Board conducted annual inspections virtually when possible to limit exposure and transmission of the COVID-19 virus.

³ The exterior door contains several glass panels that are covered with miniature venetian blinds. There is no evidence that the glass is tamper proof or that there are glass breakage alarms on the door.

- It is unclear if the metal gate has a locking mechanism from the pictures submitted and if the gate is alarmed.
- e. The Respondent-Pharmacy has expired drugs in the pharmacy. The Owner-Pharmacist was asked to submit evidence to Inspector A within seven (7) days showing that the expired drugs were sent to a reverse distributor for credit/destruction.⁴
- f. The Respondent-Pharmacy's hours of operation match the hours of operation on the Board's website. According to the dispensing log provided to the inspector, the pharmacy filled prescriptions on days that the pharmacy was supposed to be closed including: May 1, 2020; May 3, 2020; May 4, 2020; May 8, 2020; May 9, 2020; May 11, 2020; May 17, 2020; May 23, 2020; May 25, 2020; May 30, 2020; and May 31, 2020.
- g. The Respondent-Pharmacy receives packages intended for the pharmacy at the residence's front door. The Owner-Pharmacist stated he picks up the packages as soon as he hears the front doorbell.
- h. The Respondent-Pharmacy's label continues to show a P.O. Box address. The Owner-Pharmacist stated he adds an additional label with the Respondent-Pharmacy's physical address to each vial that is sent out.

- 6. On Thursday, March 21, 2019, a Board inspector ("Inspector B") attempted to conduct the "annual inspection" of the Respondent-Pharmacy. Upon arrival at 12:20 p.m., Inspector B found the Respondent-Pharmacy closed. The Respondent-Pharmacy's hours of operation on record with the Board are Tuesday, Wednesday. and Thursday, 11:00 a.m.to 2:00 p.m.
- Inspector B called the Respondent-Pharmacy and the Owner-Pharmacist answered.
 When asked to open the Respondent-Pharmacy for the Board's annual inspection,

- 10 TOTAL 1 - NO. 11 - 12 - 12 MIN

⁴ The Owner-Pharmacist has not submitted the requested evidence to date.

- the Owner-Pharmacist stated that he was not at the Respondent-Pharmacy but was out making deliveries and would not be back until 3:00 p.m.
- 8. As the Owner-Pharmacist would not be back until after the pharmacy hours of operation, Inspector B left the premises without starting the inspection.
- 9. On May 28, 2019, Inspector B returned to the Respondent-Pharmacy and completed the annual inspection.
- 10. The Inspection Form and subsequent observational memos noted the following findings:
 - a. The Respondent-Pharmacy has a box of expired drugs that needs to be sent to the reverse distributor. The dates of the drugs range from 2015 through 2019. When Inspector B asked Owner-Pharmacist if the drugs were being sent back to a reverse distributor, the Owner-Pharmacist answered that he was working on it.
 - b. The Respondent-Pharmacy is located in the basement of a residential home owned by the Owner-Pharmacist. Inspector B observed that the outside steps leading down to the Respondent-Pharmacy's public entrance was covered with wet leaves and presented a hazard for anyone trying to enter. Inspector B also observed an increased amount of insect activity at the entrance including spiders and cobwebs. When informed that he needed to mitigate the safety hazards at the public entrance to the Respondent-Pharmacy, the Owner-Pharmacist denied the presence of any hazards.
 - c. The Respondent-Pharmacy has a metal gate that separates the Respondent-Pharmacy from the rest of the residential space. The metal gate however is not on an alarm system and there are no motion detectors located in the basement area where the Respondent-Pharmacy is located.
- 11. A review of the Respondent-Pharmacy's prior annual inspection reports and Board interactions reveals that the Respondent-Pharmacy was previously put on notice of the deficiencies.

- 12. On February 16, 2017, two (2) Board inspectors ("Inspector C" and "Inspector D") conducted an annual inspection of the Respondent-Pharmacy. In addition to completing the Inspection Form, the inspectors memorialized their observations in a February 21, 2017 memo ("2017 Memo"). The Inspection Form and the 2017 Memo noted the following observations:
 - a. The Pharmacy-Respondent is located in the basement of a residence.
 - b. Upon arrival, the inspectors knocked on the basement door of the residence and observed a sign that stated "closed due to illness." As the inspectors were leaving, the Owner-Pharmacist came out of the front door of the residence and greeted the inspectors and allowed the inspection to continue.
 - c. The inspectors noted that the Respondent-Pharmacy's prescription label only includes a P.O. Box rather than the Respondent-Pharmacy's physical address.
 - d. As part of the inspection, the inspectors requested a dispensing report for the dates of February 15, 2016 through February 16, 2017. The Owner-Pharmacist was unable to provide the report at the time of the inspection. The dispensing report was emailed to the inspectors after the inspection was completed. After reviewing the dispensing report, the inspectors made the following findings:
 - 126 prescriptions were filled for a patient in Hattiesburg, Mississippi written by a prescriber in Petal, Mississippi. The prescriptions included medications and diabetic supplies. 21 of the prescriptions included controlled substances (Lorazepam 0.5 mg tablets and Acetaminophen/Codeine 325/30 mg tablets).

- ii. Eight (8) prescriptions were written by a provider in Tarzana, California for two (2) different patients with the same address as the pharmacy.
- transactions of which the majority were prescription drug items. Many of the prescriptions were filled on days when the pharmacy is officially closed (Friday, Saturday, Sunday, and Monday).

- 13. On March 13, 2014, Board Inspector A and Inspector D arrived at the Respondent-Pharmacy at approximately 10:05 a.m.⁵ to conduct the onsite Annual Inspection. After knocking several times on both the basement/pharmacy entrance and the Owner-Pharmacist's front door with no response, at 10:20 a.m. the inspectors called the Respondent-Pharmacy's phone number which went to voicemail. The inspectors noticed a car with Virginia tags in the driveway and multiple packages on the front porch.
- 14. The inspectors knocked again at 10:35 a.m. The inspectors returned to their cars and called the Respondent-Pharmacy number at 10:40 a.m., 10:50 a.m., 11:30 a.m., and 12:00 p.m., each time leaving a message. At approximately 12:19 p.m., the Owner-Pharmacist called the inspectors and explained that he had returned to the Pharmacy and was available for an inspection.
- 15. At approximately 1:00 p.m., the inspectors returned to the property. The inspectors knocked on the Respondent-Pharmacy's door with no response. The inspectors

The hours of operation were posted on the Respondent-Pharmacy's door - Monday through Friday 10am-2pm.

called the pharmacy again and were finally granted access by the Owner-Pharmacist.

- 16. The inspectors memorialized their findings in the Inspection Report and a letter dated March 18, 2014 ("2014 Letter"). The Inspection Report and 2014 Letter stated in part:
 - a. The Respondent-Pharmacy is located in the basement of a residential property.
 - b. The Respondent-Pharmacy does not have an alarm system.
 - c. The address on the prescription label is a P.O. Box rather than the Respondent-Pharmacy's physical address.
 - d. The pharmacy area contains children's toys and a set of exercise weights.
 - e. When asked how the Respondent-Pharmacy verifies a doctor-patient relationship when filling mail order prescriptions, the Owner-Pharmacist replied that he knows all of his patients, so he doesn't need to verify a doctor-patient relationship.
 - f. When asked for the perpetual inventory log, the Owner-Pharmacist provided Inspector A with six (6) sheets of paper. Out of the six (6) sheets of paper, there was only one (1) Schedule II drug in stock (Oxycodone APAP 5/325mg). When asked if there were any additional scheduled drugs in the pharmacy, the Owner-Pharmacist stated that the Oxycodone was the only one. Inspector D located two (2) additional narcotics bottles (Methylphenidate 10 mg and Dextro-Methamphetamine 20 mg) in a drawer with the Schedule II invoices and brought it to the Owner-Pharmacist's attention. There were no perpetual inventory logs for these two (2) additional Schedule II narcotics.
 - g. When reviewing the Schedule II prescriptions, the Respondent-Pharmacy failed to include a copy of the prescription label on the back of the prescription making it impossible for the inspectors to determine their fill date. The inspectors located one hard copy prescription from a New York prescriber that was filled a year after the prescription had been written.

- h. The Respondent-Pharmacy failed to maintain a minimum of two (2) years of documentation that employees had completed mandatory annual training regarding the role and responsibility of pharmacy staff in preventing medication errors. The last recorded training was completed in 2012.
- i. The sink located in the Respondent-Pharmacy was filled with books and paper. The Owner-Pharmacist informed the inspectors that he uses water from the laundry room (located outside the enclosed pharmacy area) for the pharmacy.
- j. There were five (5) expired medications found on the counter mixed in with current dated drugs. The Owner-Pharmacist disputed that the expired medications were on the counter.

- 17. On June 9, 2011, at 10:00 a.m., a Board inspector ("Inspector E") attempted to conduct an annual/investigatory inspection. The Pharmacy door was locked and there was no answer at the door.
- 18. On June 15, 2011, Inspector D and Inspector E were granted access to the Respondent-Pharmacy to complete an annual/investigatory inspection. The inspectors memorialized their visit in a memorandum dated June 15, 2011 ("2011 Memo"). The 2011 Memo identified the following issues:
 - a. The Respondent-Pharmacy is located in a residential neighborhood. It is located in the basement of the Owner-Pharmacist's residence.
 - b. The inspectors noted flying bugs congregating at the entrance of the Respondent-Pharmacy.
 - c. There was minimal signage on the door listing only the hours of operation. There was no signage with the Respondent-Pharmacy's name on the door.
 - d. The Respondent-Pharmacy does not have an alarm system.

- e. Weight training equipment was observed in the pharmacy area.
- f. The Owner-Pharmacist attempted to prevent Inspector D from taking photographs of the pharmacy area as part of the inspection. In several photographs you can see the Owner-Pharmacist attempting to block the camera's view with his hand.

II. CONCLUSIONS OF LAW

Based on the foregoing Findings of Fact, the Board concludes as a matter of law that the Respondent-Pharmacy violated the following provisions of the Act:

Health Occ. § 12-403. Required Standards.

- (c) In general. Except as otherwise provided in this section, a pharmacy for which a pharmacy permit has been issued under this title:
 - (1) Shall be operated in compliance with the law and with the rules and regulations of the Board;
 - (2) Shall be located and equipped so that the pharmacy may be operated without endangering the public health or safety;
 - (3) Shall ensure that a licensed pharmacist be immediately available on the premises to provide pharmacy services at all times the pharmacy is in operation;

(11)(ii) Shall:

.

- 1. Be equipped with the minimum equipment and appliances specified by the Board under this section; and
- 2. Be kept in a clean and orderly manner;
- (12) Shall store all prescription or nonprescription drugs or devices properly and safely subject to the rules and regulations adopted by the Board;

- (16) Shall provide such personnel, automation, and technology as are necessary to comply with the labeling requirements specified in § 12-505 of this title;
- (21) Shall dispense or dispose of prescription drugs or medical supplies in accordance with Title 15, Subtitle 6 of the Health-General Article[.]

Health Occ. § 12-413. Entry and inspection.

- (a) During business hours, the Secretary, the Board, or the agents of either may enter any permit holder's pharmacy and inspect for compliance with federal and State laws and regulations:
 - (1) Any drugs or devices, dentifrices, domestic remedies, and toilet articles that are in the pharmacy;
 - (2) Any records or publications that are required to be kept by a pharmacy under this title; and
 - (3) The facility.

. . . .

(c) A person may not hinder an inspection or an investigation conducted under this section.

Health Occ. § 12-505. Labeling requirements for prescription medications.

- (a) Except for a drug or device dispensed to an inpatient in a hospital or related institution, each container of a drug or device dispensed shall be labeled in accordance with this section.
- (b) In addition to any other information required by law, the label shall include:
 - (1) The date the prescription is filled;

Health Gen. § 21-221. Prescription Drug Labeling.

- (a) A drug that is dispensed under a prescription shall bear a label that states:
 - (1) The name and address of the dispenser;

The pertinent provisions of COMAR 10.34 provide as follows:

10.34.05.02. Prescription Area

- A. The pharmacy permit holder shall:
 - (2) Provide a means of securing the prescription area;
 - (4) Monitor unauthorized or emergency entry after the prescription area has been secured by the pharmacist; and
- C. Security

. . . .

- (1) A pharmacy shall be secure from unauthorized entry as follows:
 - (a) Access from outside the premises shall be:
 - (ii) Well controlled
- (2) A pharmacy shall be equipped with:
 - (a) An alarm system to detect entry after hours;
 - (b) A security system that provides protection against theft and diversion;
 - (e) A security system to protect the integrity and confidentiality of data and documents limited to authorized personnel[.]

10.34.05.03. Pharmacy Operations

A. A pharmacist shall be immediately available on the premises to provide pharmacy services at all times the pharmacy is in

operation.

10.34.12.01. Removal of Expired Medications

B. A wholesale distributor, pharmacist, or pharmacy shall have adequate and credible provisions for return of outdated drugs, including but not limited to partials, through its wholesale distributor or reverse distributor.

10.34.14.02. Opening a Pharmacy

B. A pharmacy may not be located in a residence.

III. ORDER

ORDERED that the Respondent-Pharmacy's permit shall be placed on Probation for a period of at least THREE (3) YEARS, subject to the following terms and conditions:

- 1. The Respondent-Pharmacy shall install an alarm system to provide security for the perimeter of the Respondent-Pharmacy. The Respondent-Pharmacy shall submit documentation of installation and the specifics of the alarm system to the Board within SIXTY (60) DAYS of the date of this Consent Order;
- 2. The Respondent-Pharmacy shall provide documentation that the Respondent-Pharmacy has been in contact with the Montgomery County Department of Permitting Services (specifically the Zoning, Well & Septic and Code Compliance Division) and that the Respondent-Pharmacy is in compliance with all applicable county codes/ordinances within SIXTY (60) DAYS of the date of this Consent Order;

- 3. The Respondent-Pharmacy shall submit quarterly reverse distribution reports to the Board to ensure compliance with COMAR 10.34.12.01(B);
- 4. The Respondent-Pharmacy will make changes to its exterior signage (including at the residence's front door) to clarify that all deliveries for the Respondent-Pharmacy shall only be delivered at the primary exterior door to the Respondent-Pharmacy;
- 5. The Respondent-Pharmacy shall not dispense prescriptions out of state unless the Respondent-Pharmacy holds the proper out-of-state permits;
- 6. During the probationary period, the Board, at its discretion, may conduct random inspections of the Respondent-Pharmacy;

ORDERED that after THREE (3) YEARS from the date of this Consent Order, the Respondent-Pharmacy may submit a written petition to the Board requesting termination of probation, provided that it has been fully compliant with this Consent Order and has no outstanding complaints filed against it; and it is further

ORDERED that the Respondent-Pharmacy shall operate in accordance with the laws and regulations governing the practice of pharmacy in Maryland; and it is further

ORDERED that the Respondent-Pharmacy shall bear the cost(s) of complying with the Consent Order; and it is further

ORDERED that the Respondent-Pharmacy shall at all times cooperate with the Board in the monitoring, supervision, and investigation of its compliance with the terms and conditions of this Order; and it is further

ORDERED that failure to comply with the terms and conditions of the Consent Order, including failure to pay the monetary fine in full by the deadline, constitutes a violation of the Consent Order and the Board, in its discretion, after notice and an

opportunity for a show cause hearing before the Board, may impose any appropriate sanction under the Act; and it is further

ORDERED that the Consent Order shall be a public document pursuant to Md. Code Ann., Gen. Prov. §§ 4-101 et seq. (2014).

5-3-21

Deena Speights Napata Executive Director, for

Kevin Morgan, Pharm.D., President

State Board of Pharmacy

CONSENT

I, Majid Danesh, R.Ph., owner of Pharmaceutical Services of America, acknowledge that I have had the opportunity to consult with legal counsel before signing this document. By this Consent, I accept, on behalf of Pharmaceutical Services of America, to be bound by this Consent Order and its conditions and restrictions. On its behalf, I waive any rights Pharmaceutical Services of America may have had to contest the Findings of Fact and Conclusions of Law.

I acknowledge the validity of this Consent Order as if entered into after the conclusion of a formal evidentiary hearing in which Pharmaceutical Services of America would have had the right to counsel, to confront witnesses, to give testimony, to call witnesses on its behalf and to all other substantive and procedural protections as provided by law.

I acknowledge the legal authority and the jurisdiction of the Board to initiate these proceedings and to issue and enforce this Consent Order. I also affirm that I am waiving Pharmaceutical Services of America's right to appeal any adverse ruling of the Board that might have followed any such hearing.

I sign this Consent Order without reservation, and I fully understand and comprehend the language, meaning and terms of this Consent Order. I voluntarily sign this Order on behalf of Pharmaceutical Services of America and understand its meaning and effect.

Date

Majid Danesh, R.Ph., Owner

Pharmaceutical Services of America

NOTARY

STATE OF Maryland
COUNTY/CITY OF: Montgomery
I hereby certify that on this 7th day of April , 2021, before me, a Notary
Public of the State of Morgand and County/City aforesaid, personally appeared
Majid Danesh, R.Ph., and made an oath in due form that the foregoing Consent was his
voluntary act and deed.
AS WITNESSETH my hand and notarial seal.
Notary Public

My Commission Expires: Nov 06, 2023

MILTON FLORES
Notary Public
Montgomery County, Maryland
My Commission Expires
November 06, 2023